K082891

# 510(K) SUMMARY

**Date Prepared** October 16, 2009

## SPONSOR/510(K) OWNER/ MANUFACTURER

Haag-Streit AG
Gartenstadtstrasse 10
Koeniz, Berne, Switzerland CH-3098
Telephone: 011-41319780209
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Email: rudolf.waelti@haag-streit.ch
Establishment Registration Number: 1000176188

OCT 20 2009

## OFFICIAL CONTACT PERSON

Lena Sattler
Orasi Consulting, LLC.
1667 Ridgewood Rd.
Wadsworth, OH 44281
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## COMMON/USUAL NAME

Device, Analysis, Anterior Segment

## PROPRIETARY NAMES

LENSTAR LS 900
Allegro Biograph

## CLASSIFICATION INFORMATION

| | |
|---|---|
| Classification Name: | Device, Analysis, Anterior Segment |
| Medical Specialty: | Ophthalmic |
| Device Class: | II |
| Classification Panel: | Ophthalmic Device Panel |
| Product Codes: | MXK – Device, Analysis, Anterior Segment |

## PRODUCT CODE: CLASSIFICATION / CFR TITLE

| | |
|---|---|
| MXK: | Class II § 21 CFR 886.1850 |

## LEGALLY MARKETED PREDICATE DEVICES

| | |
|---|---|
| Trade/Device Name: | IOLMaster |
| Applicant: | Carl Zeiss Inc. |
| 510(k) Premarket Notification number: | K993357 |
| Classification: | Class II |
| FDA Product Code: | HJO – Biomicroscope, Slit Lamp, AC Powered |
| Establishment Registration number: | 9615030 |
| Trade/Device Name: | Optical Low Coherence Reflectometry Pachymeter (OLCR) |
| Applicant: | Haag-Streit AG |
| 510(k) Premarket Notification number: | K030393 |
| Classification: | Class II |
| FDA Product Code: | MXK – Device, Analysis, Anterior Segment |
| Establishment Registration number: | 1000176188 |
| Trade/Device Name: | Accusonic A-Scan Model 24-4000 |
| Applicant: | Accutome |
| 510(k) Premarket Notification number: | K032956 |
| Classification: | Class II |
| FDA Product Code: | IYO – System, Imaging, Pulsed echo |
| Establishment Registration number: | 2521877 |
| Trade/Device Name: | Keratron |
| Applicant: | Alliance Medical Marketing |
| 510(k) Premarket Notification number: | K944616 |
| Classification: | Class I |
| FDA Product Code: | HLQ-Keratoscope |
| Establishment Registration number: | 1058327 |

## GENERAL DEVICE DESCRIPTION

The LENSTAR LS 900 is a non-invasive, non-contact system for measuring the parameters of the human eye required to determine the appropriate IOL for implantation and to calculate the optimal power of the IOL. The LENSTAR LS 900 measures: axial eye length, corneal thickness, anterior chamber depth, lens thickness, radii of curvature of flat and steep meridian, axis of flat or step meridian, white to white distance and pupil diameter.

## INDICATIONS FOR USE

The LENSTAR LS 900 is a non-invasive, non-contact OLCR (Optical Low Coherence Reflectometry) Biometer used for obtaining ocular measurements and performing calculations to assist in the determination of the appropriate power and type of IOL (intraocular lens) for implantation after removal of the natural crystalline lens following cataract removal. The LENSTAR LS 900 measures:

- Axial eye length
- Corneal thickness
- Anterior chamber depth
- Aqueous depth
- Lens thickness
- Radii of curvature of flat and steep meridian
- Axis of the flat meridian
- White to white distance
- Pupil diameter

## SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The LENSTAR LS 900 and the predicate devices are substantially equivalent because they use similar technology and perform similar functions to provide the ocular measurements and to perform calculations needed to allow a physician to choose the appropriate power and type of IOL for a patient eye.

## CLINICAL SUMMARY

Two prospective, non-randomized, single site comparison studies were performed to substantiate equivalence of the LENSTAR LS 900 to the stated predicate FDA approved medical devices including the IOL-Master (Carl Zeiss Meditec AG), the OLCR (Haag-Streit AG), the Accusonic A-Scan (Accutome) and Keratron (Alliance Medical Marketing). The studies were approved by an ethics committee. The studies were conducted in Berne, Switzerland.

Data includes measurements of axial length, central corneal pachymetry, anterior chamber depth, central lens thickness, average corneal radius, flat corneal axis, white-to-white distance and pupillometry.

Analysis of clinical data substantiates equivalence between the measurement data of the LENSTAR LS 900 with the all predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Haag-Streit AG
c/o Ms. Lena Sattler
Official Correspondent
Orasi Consulting, LLC
1667 Ridgewood Road
Wadsworth, OH 44281

OCT 20 2009

Re: K082891
Trade/Device Name: Haag-Streit LENSTAR LS 900
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered Slitlamp Biomicroscope
Regulatory Class: II
Product Code: HJO
Dated: October 16, 2009
Received: October 19, 2009

Dear Ms. Sattler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kevia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082891

Device Name: LENSTAR LS 900

Indications for Use:

The LENSTAR LS 900 is a non-invasive, non-contact OLCR (Optical Low Coherence Reflectometry) Biometer used for obtaining ocular measurements and performing calculations to assist in the determination of the appropriate power and type of IOL (intraocular lens) for implantation after removal of the natural crystalline lens following cataract removal. The LENSTAR LS 900 measures:

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- Axis of the flat meridian
- White to white distance
- Pupil diameter

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K082891